

Application No. 09/733,640

**REQUEST FOR RECONSIDERATION**

Applicants would like to thank Examiner Gollamudi for indicating that claim 35 is free of the prior art. Applicants would also like to thank Examiner Gollamudi, as well as her supervisor, for the courteous and helpful discussion held with Applicants' representative on September 13, 2002. During this discussion, it was suggested that the claims specify either a multilayered composition, or a method that included injecting. Applicants have now amended the claims in line with this suggestion.

Drug release from polymeric implants is typically provided by a solution of a biodegradable polymer and a bioactive agent in a biocompatible solvent. The solution solidifies upon injection into the body to form a polymeric implant from which the agent is released. In some instances, this method yields zero-order release kinetics. However, zero-order release kinetics are not ideal for all therapies, and there is a need for biodegradable implants that can have a variety of drug release characteristics.

The present invention includes a composition for controlled release of a bioactive agent, comprising a biodegradable crystallizable polymer, a biodegradable amorphous polymer, a biocompatible solvent, and a bioactive agent. As now claimed, the present invention is directed to multilayered compositions or a method of administering a bioactive agent including injecting.

The rejection of the claim 1, 5-7, 17-18, 21, 22, 25, 27-34, 36, 38, 40 and 41 under 35 U.S.C.103 over Tipton et al., and Domb et al.; and claims 2-4, 8, 10-13, 19, 20, 23, 24, 26, 37, and 42-47 under 35 U.S.C.103 over Tipton et al., Domb et al. and Brodbeck et al.; has been obviated by appropriate amendment. Claim 1 now specifies that the compositions are multilayered; claim 35 has been incorporated into claim 34, now in independent form; and the remaining claims not dependent on claims 1 and 34 have been cancelled.

Tipton et al. describes a biodegradable film dressing which can be used to protect and/or deliver a bioactive agent to an area of tissue (col. 2, lines 5-12). The Examples (1-10) describe biodegradable compositions applied externally as films. There is no description of multilayered compositions, nor injection of compositions.

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Domb et al. has been cited for polymer blends suitable for as use of carriers for active agents; multilayered compositions are not described. Brodbeck et al. has been cited for specific limitations of dependent claims.

The claims now specify either (a) a composition that is multilayered, or (b) a method including injecting. Tipton et al. describes compositions applied externally as films; there is no description of multilayered compositions, nor injection of compositions. Domb et al. has been cited for polymer blends and Brodbeck et al. has been cited for specific limitations of dependent claims. There is no description of multilayered compositions. Applicants submit that the claimed invention is neither anticipated by, nor obvious over, the applied references. Withdrawal of these rejections is respectfully requested.

Applicants submit that the application is in condition for allowance. Early notice of such action is respectfully requested.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Twice Amended) A composition for controlled release of a bioactive agent, comprising:

a biodegradable crystallizable polymer;

a biodegradable amorphous polymer;

a biocompatible solvent; and

a bioactive agent,

wherein the composition is multi-layered.

34. A method of administering a bioactive agent, comprising: inserting [the] a composition for controlled release of a bioactive agent [of claim 1] into an organism,  
wherein the composition comprises:

a biodegradable crystallizable polymer;

a biodegradable amorphous polymer;

a biocompatible solvent; and

a bioactive agent, and

wherein the inserting is by injecting.